DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 13, 2015

BIO-RAD LABORATORIES
SUZANNE PARSONS
REGULATORY AFFAIRS MANAGER
9500 JERONIMO ROAD
IRVINE CA 92618

Re: K143379
Trade/Device Name: Liquichek Maternal Serum II Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Code: JJY
Dated: February 9, 2015
Received: February 11, 2015

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -A

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143379

Device Name
Liquichek Maternal Serum II Control

Indications for Use *(Describe)*
Liquichek Maternal Serum II Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

Analytes are: AFP
hCG
Unconjugated Estriol
Inhibin A

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Liquichek Maternal Serum II Control

1.0 Submitter

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Contact Person

Suzanne Parsons
Regulatory Affairs Manager
Telephone: (949) 598-1467

Date of Summary Preparation

March 12, 2015

2.0 Device Identification

Product Trade Name:	Liquichek Maternal Serum II Control
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek Maternal Serum Control
Bio-Rad Laboratories
Predicate 510(k) Number: K984594

4.0 Description of Device

Liquichek Maternal Serum II Control is prepared from defibrinated human plasma with added constituents of human origin, chemicals, stabilizers, and preservatives. The control is provided in liquid form for convenience.

Table 1: Product Catalog Description

Level	Configuration
Liquichek Maternal Serum II Control Level 1	6 x 2.5 mL
Liquichek Maternal Serum II Control Level 2	6 x 2.5 mL
Liquichek Maternal Serum II Control Level 3	6 x 2.5 mL
Liquichek Maternal Serum II Control Trilevel MiniPak	3 x 2.5 mL (1 vial per level)

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

5.0 Intended Use

Liquichek Maternal Serum II Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

6.0 Comparison of the New Device with the Predicate Device

Liquichek Maternal Serum II Control claims substantial equivalence to Lyphochek Maternal Serum Control (*K984594*). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

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a **Table 2:** Similarities and Differences Between the New Device and the Predicate Device

Characteristics	Liquichek Maternal Serum II Control (*New Device*)	Lyphochek Maternal Serum Control (*Predicate Device, K984594*)
Similarities		
Intended Use	Liquichek Maternal Serum II Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Same
Base Matrix	Defibrinated Human Plasma	Same
Differences		
Form	Liquid	Lyophilized
Fill Size	2.5 mL	5 mL
Thawed and Unopened Stability	40 days at 2 to 8°C	No claims made
Thawed and Opened Vial / After Reconstitution	30 days at 2 to 8°C	10 days at 2 to 8°C
Shelf Storage & Stability (Unopened)	-20 to -70°C until the expiration date	2 to 8°C until the expiration date
Analytes	**Contains:** AFP hCG Estriol, Free Inhibin A	**Contains:** AFP hCG Estriol, Free **Does not contain:** Inhibin A

7.0 Traceability:

The analytes contained in the Liquichek Maternal Serum II Control are obtained from commercially available sources, except for Inhibin A which is internally sourced.

8.0 Value Assignment

The mean values and corresponding ±3SD ranges printed in the insert were derived from replicate analyses and are specific for the lot of the product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during

the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

9.0 **Stability:**

Real time stability studies were performed to establish thawed (opened and unopened vial) stability claims. Accelerated stability studies were performed to establish the shelf life stability claims with real-time stability ongoing. The stabilities for Liquichek Maternal Serum II Control are as follows:

Thawed and Unopened Stability	40 days at 2 to 8°C
Thawed and opened Stability	30 days at 2 to 8°C
Shelf Life Stability:	40 months at -20 to -70°C

10.0 **Conclusion**

Based on the performance characteristics indicated above, Liquichek Maternal Serum II Control is substantially equivalent to the predicate device (K984594).

All supporting data is retained on file at Bio-Rad Laboratories.